

REMARKS

The Office Action mailed on May 08, 2003, has been reviewed and the comments of the Patent and Trademark Office have been considered. Prior to this paper, claims 1-11 were pending in the present application. By this paper, Applicants add claims 12-24. Therefore, claims 1-24 are now pending in the present application.

Applicants respectfully submit that the present application is in condition for allowance for the reasons that follow.

Indication of Allowable Subject Matter

Applicants thank Examiner Roberts for the indication that claims 4 and 5 contain allowable subject matter, and that claims 9 and 10 are allowed.

Reference Characters

Reference characters have been retained in the claims but have no effect on the claim scope per MPEP § 608.01(m)

Affirmation of the March 28, 2003 Provisional Election of Species

In response to the Office Action dated May 8, 2003, Applicants hereby affirm their election of species of Fig. 13 for prosecution in the subject application. Claims 1-5, and 7-11 are readable on the elected species. Claims 1-5 and 7-11 are generic.

Applicants note that claim 6 is dependent from a claim that has been identified as a generic claim, claim 4. Applicants further note that claim 4 has been indicated as containing allowable subject matter. Thus, Applicants respectfully request that claim 6 be rejoined for consideration and allowance.

Applicants, of course, continue to reserve the right to file one or more divisional applications covering any non-elected subject matter.

Claim Rejections Under 35 U.S.C. §103(a)

In the Office Action, Claims 1-3 and 7-8 are rejected under 35 U.S.C. §103(a) as being unpatentable over Erlebacher (USP 5,350,399) in view of Sugarbaker (USP 5,928,264). Applicants respectfully traverse the rejection as to the claims above, and submit that these claims are allowable for at least the following reasons.

Applicants rely on MPEP § 2143, which states that:

[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

It is respectfully submitted that at least the first and third criteria of MPEP § 2143 have not been met in the Office Action.

The Cited References Do Not Suggest All Claim Recitations

Even if the first requirement of MPEP § 2143 was satisfied in the Office Action (which it is not, as explained below), the cited references still do not meet the third requirement, which is that “the prior art reference (or references when combined) must teach or suggest all the claim limitations.”

Neither Erlebacher nor Sugarbaker, alone or in combination, disclose, teach or suggest a device or method for closing a wound according to the present invention. Specifically, neither reference teaches a device adapted to convert movement of a wound closing tool away from the wound to a pushing movement to move a proximal plug member in a direction towards a distal plug member.

The wound closing tool according to claim 1 is configured to close a wound by moving a proximal plug member positioned outside the vessel towards a distal plug member positioned inside a vessel (as exemplary illustrated in Figs. 1 and 2 of the specification) by

pulling the tool away from the distal plug member. In one embodiment, the tool is configured with a gear mechanism that is coupled to a retracting means (for example, a suture 6). By way of exemplary embodiment, when the tool is pulled away from the wound (or, more specifically, when the cover 150 containing the gear racks 170 are pulled away from the wound), a rotation is imparted on the gears of the gear mechanism because the plate on which the gears are rotateably mounted interfaces with the retracting means to resist movement of the plate away from the wound. The rotation then imparts a force on cogs 163 that pushes the proximal plug member in the opposite direction from the pulling movement of the tool because the cogs 163 interface with the gears on the opposite side from the racks 170 (see Fig. 9).

In contrast, the device of Erlebacher functions much like a rivet gun. That is, by *squeezing* the trigger 28, the positioner member 26 is actuated *forward*, collapsing the occluder 13 in position. Jaws 46 clamp down on guide 12 to *react against backward* movement of the gun, thus preventing the gun from moving backward. That is, the Erlebacher's device does not move in a proximal direction *away* from the wound when clamping together two distal and proximal plug members, and there is no backward force exerted on the gun to push occluder 13 towards the wound.

The Sugarbaker reference does noting to remedy the above discussed deficiencies of Erlebacher. In Sugarbaker, all movement of the device results in the actuation of a component without movement of the device away from a wound or the application of force in a direction away from a wound.

Also, the Sugarbaker reference fails to disclose a gear mechanism for converting a vector movement in one direction into a vector movement in another direction (or even in a parallel but offset direction). Each example provided in Sugarbaker teaches the conversion of a vector movement into a rotational movement (e.g. by pressing block 34 of Fig. 1, pinions 24 and 26 rotate) or the conversion of a rotational movement into a vector movement (e.g. rotating driving gear 82 of Fig. 16, tine 16 is withdrawn into the housing 8). That is, Sugarbaker does not disclose, teach, or suggest the conversion of a vector movement in one direction into a vector movement into another direction. Ehrlebacher does not remedy this

deficiency, as it is limited to the conversion of a rotational movement of the trigger to a vector movement of the positioner member 26.

* * * * *

Claims 7-8 recite that “the distal plug member comprises a *through bore* (8), and a suture (6) is *passed through said bore* (8) to serve as the retracting means *by providing an enlarged portion at one end as a counter* when pulling the suture.” (Emphasis Added.) It is respectfully submitted that neither Erlebacher nor Sugarbaker disclose, teach, or suggest such recitations.

The device of Erlebacher does indeed teach an intra-arterial occluder 11 and an extra-arterial occluder 13, along with a guide 12 spanning the distance between the occluder. Intra-arterial occluder 11 is identified in the Office Action as satisfying the requirements of the distal plug member. However, there is no “through bore” in the occluder 11 and “a suture passed through said bore” in Erlebacher. Erlebacher teaches a “guide means in the form of an elongated . . . wire 12 *integral with and extending centrally from the intra-arterial occluder 11.*” (Col. 5, lines 32-37, emphasis added.) That is, the wire 12 is part of the occluder 11, and there is no through bore in occluder 11, and thus, there can be no suture passed through a through bore in occluder 11. This is clearly seen in Figs. 7-10 of Erlebacher, where the occluder 12 is shown with a hole 15 and the occluder 11 is not shown with a hole.

The Office Action characterizes the gap between elements 53 as “the through bore.” Elements 53 are pincers used to cut the guide 12. (See Erlebacher, col. 7, lines 50-55.) They are not part of Erlebacher’s occluder 11 or occluder 12. Thus, assuming *arguendo* that the gap between pincers 53 is a bore, the bore is not in a “distal plug member,” as is required by the claims.

The Sugarbaker reference does not remedy these deficiencies for at least the reason that it does not teach a plug. This is not surprising, as the teachings of Sugarbaker are entirely directed towards grasping tissue. Therefore, claim 7 is allowable due to the deficiencies of the cited references. Claims 8 and 11 which depend from claim 7 are allowable at least due to their dependency from claim 7, and for the applicable reasons above. Reconsideration is respectfully requested.

In sum, even if the first requirement of MPEP § 2143 is satisfied, the third requirement of MPEP § 2143 is not satisfied in the Office Action, since neither reference teaches or suggests each and every element of the present invention. Thus, the present claims are allowable.

Lack of Suggestion or Motivation to Modify or Combine the References

MPEP § 2143.01, subsection 6 states that “the proposed modification cannot change the principle of operation of a reference – If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810 (CCPA 1959).” That is, a reference cannot be modified if the modification changes the principle of operation of the reference.

The present invention operates by converting a movement of the tool in a proximal direction away from the wound to a pushing movement in a direction towards the wound. As discussed above, neither of the cited references operate in this manner; both having a rotational movement either as the input movement or the resulting movement. With this in mind, it is respectfully submitted that modifying either of the cited references to utilize the gear arrangement claimed in the present invention would change the principle of operation of the cited references. Therefore, the teachings of the cited references are not sufficient to render the claims *prima facie* obvious.

* * * * *

Claim 11, which was not addressed in the Office Action (discussed below), is allowable for at least the applicable reasons discussed above. Allowance of claim 11 is respectfully requested.

Claim 11 has not been addressed in the May 08 Office Action

Applicants note that on December 18, 2001, a preliminary amendment was filed to, *inter alia*, amend claims 4 and 8 and add claim 11. A copy of this preliminary amendment is attached in Appendix A of this response, along with a copy of the filing receipt. Applicants

respectfully request that claim 11 be examined, and further request that in the event that a second office action containing rejections of one or more of the claims is issued by the Patent Office, this second office action be made a non-final office action.

New Claims

As seen above, Applicants have added new claims 12-24. Support for these new claims can be found, among other places, in claims 1-11.

Applicants respectfully submit that new claims 12-24 are allowable for at least the reasons that make claims 1-11 allowable, as discussed above.

Applicants submit that claims 12-16 and 18-24 read on the elected species for the same reasons that claims 1-5 and 7-10 read on the elected species. Claim 17 is dependent from claim 15, which should be considered a generic claim for the same reasons that make claim 4 a generic claim. As claim 15 is allowable, claim 17 should be allowed as well.

Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

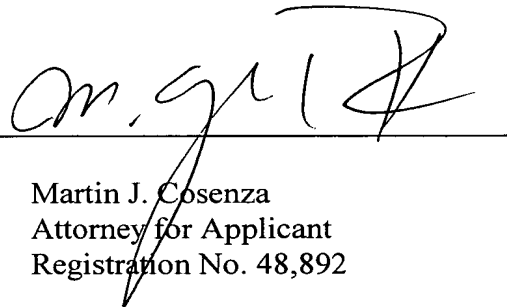
Examiner Roberts is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date August 8, 2003

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143
Telephone: (202) 295-4747
Facsimile: (202) 672-5399

By

A handwritten signature in black ink, appearing to read "M. J. Cosenza", is written over a horizontal line. The signature is stylized with a large, sweeping initial "M" and a distinct "J".

Martin J. Cosenza
Attorney for Applicant
Registration No. 48,892